

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments in which claims 8, 11-15 and 19 are pending, claims 8, 11-13, 15 and 19 have been amended, and claims 1-7, 9-10, and 16-18 are cancelled.

Rejections Under 35 USC § 112

The claims have been amended to render the 112 rejections moot. Specifically, the term prodrug has been deleted from the claims; claim 15 contains a positive recitation of how the method is practiced; claims 16 and 17, and the phrase “an effective amount of” has been added to claim 19.

Rejections Under 35 USC § 101

Claim 18 has been cancelled, rendering this rejection moot.

Rejections Under 35 USC § 102

Applicants have amended the claims to render this rejection moot. The definition of (X1)(X2)(X3) is now respectively (heteroaryl)(linker)(heteroaryl), which is not described in U.S. Patent Nos. 6,384,075 and 6,172,113.

Rejections Under 35 USC § 103

The Examiner has made a rejection under 35 USC 103(a) citing two patents of the present assignee that are not in fact prior art under the safe harbor provision of 35 USC § 103(c). These are US Patent Nos. 6,384,075 and 6,172,112, which issued on May 7, 2002 and January 9, 2001, respectively. Section 103(c) is reproduced below.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. (Emphasis added).

MPEP §§ 706(l)(1)-(3) discuss in detail how examiners are to handle the safe harbor provision of section 103.

Therefore in accordance with 35 USC 103(c) and MPEP §§ 706(l)(1)-(3), the undersigned attorney of record states that, the present application and US Patent Nos. 6,384,075 and 6,172,112 were, at the time the invention of the present application was made, owned by Shionogi & Co., Ltd. In accordance with MPEP § 706.02(l)(2), this statement is sufficient to disqualify US Patent Nos. 6,384,075 and 6,172,113 from being used as prior art in a rejection for obviousness against the present claims.

Rejections for Judicially Created Double Patenting

In response to the rejection for judicially created double patenting over US Patent Nos. 6,384,075 and 6,172,113, applicants contend that this rejection is improper for the following reasons.

Applicants contend that the compound of amended claim 8 is unobvious over U.S. 6,384,075 and 6,172,113 because the compound has an antagonistic activity against not only a PGD₂ receptor but also a TXA₂ receptor. U.S. Patent Nos. 6,384,075 and 6,172,113 do not describe or suggest the antagonistic activity against a TXA₂ receptor. A compound having a dual antagonistic activity against both a TXA₂ receptor and a PGD₂ receptor is useful as a therapeutic agent for various diseases caused by TXA₂ or PGD₂. For example, in the case of bronchial asthma, it is known that TXA₂ cause potent tracheal contraction and respiratory anaphylaxis and PGD₂ effects infiltration of eosinophils. TXA₂ and PGD₂ are thought to be one of causative substances of the pathopoiesis and advance of asthma, thus the dual antagonistic compounds are expected to be more potent agents for treating asthma than known antagonists that act against a single receptor. Further, in the case of allergic rhinitis, it

is recognized that TXA₂ and PGD₂ cause the swelling of nasal mucosa through the aggravation of vascular permeability, and PGD₂ induces the nasal blockage through the enlargement of vascular volume. Therefore, dual antagonistic compounds are expected to be more potent agents for treating nasal blockage than known antagonists. These diseases and condition thereof might be treated by administering both a TXA₂ receptor antagonist and a PGD₂ receptor antagonist at the same time, for example, in combination therapy or as a mixture thereof. But the administration of two or more agents often causes some problems due to the difference of their metabolic rate. For example, when the antagonists are different from each other in the time to reach a maximum blood concentration or the duration of action, they do not always efficiently exhibit each receptor antagonistic effect at the same time, failing to give a desired additive or synergic effect. The present invention thereby unexpectedly overcomes these disadvantages of the presently known compounds.

Provisional Rejections for Judicially Created Double Patenting

With respect to the rejection for judicially created double patenting, applicants contend that this rejection is improper for the following reasons. Applicants request that the Examiner withdraw the provisional judicially created double patenting rejection over Application No. 10/297,065. With the submission of this response, applicants believe that all outstanding rejections have been overcome. MPEP § 804 I. B., reproduced below, states that when a provisional double patenting rejection is the only rejection remaining, the Examiner should withdraw the rejection and allow the application to issue as a patent.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

If the "provisional" double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent.


Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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